

National Imaging Associates, Inc.*	
Clinical guidelines	Original Date: September 1997
PET SCANS <u>:</u>	
<u>includes</u>	
• PET	
 PET with CT Attentuation 	
• PET/CT	
	Last Revised Date: June May 2022
Guideline Number: NIA_CG_070-1	Implementation Date: January 20223

GENERAL NOTES:

ADULT AND PEDIATRIC MALIGNANCIES¹: ONCOLOGICAL PET IS INDICATED FOR BIOPSY-PROVEN CANCER OR STRONGLY SUSPECTED CANCER BASED ON OTHER DIAGNOSTIC TESTING. The appropriateness of an ordered PET/CT study is dependent on which radiopharmaceutical will be used for the PET/CT.

FDG-PET/CT (fluorodeoxyglucose-positron emission tomography)

LUNG NODULE seen on LDCT or CT+ contrast (without known malignancy)

- Solid Component of Dominant Nodule (either solitary or clearly dominant) ≥ 8mm and <3cm or Part solid/mixed nodules with the solid component 8 mm or larger
- Mixed nodule (i.e., ground glass and solid nodule) with solid component of the nodule ≥ 4mm on LDCT when there has been
 - Interval growth of the solid component of at least 1.5mm on subsequent LDCT scans

OR

 Interval development of a new mixed nodule on subsequent LDCT with the solid nodule component ≥ 4mm

NOTE: >3cm is considered a MASS; therefore, a tissue type is <u>usually</u> needed prior to <u>PET (to determine if SCLC vsor NSCLC)</u>. determining if a PET is approvable (ie need to know whether the lung cancer is small cell or non-small cel. However, if the chest CT imaging findings meet criteria for limited stage SCLC | and no prior imaging shows metastatic disease elsewhere, PET can be approved prior to biopsy to determine if meets approval see GL) in order to guide

^{*} National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

^{1—} PET Scan

biopsy of any FDG_avid adenopathy at the same time the primary is biopsied. If disease clearly is in both sides of the chest and/or outside the chest, then PET is not needed/approvable prior to tissue diagnosis.

USEFUL DEFINITIONS (to aid in using the following table(s))

- **INITIAL STAGING** refers to imaging that is performed AFTER the diagnosis of cancer is made, and generally before any treatment.
- RESTAGING includes scans that are either needed during active treatment*
 (subsequent treatment strategy**) to determine response to treatment, within 6
 months after the end of treatment, or when there is clinical concern for recurrence
 (i.e., new imaging, new signs, rising labs/tumor markers or symptoms relative to
 type of cancer and entire clinical picture) (recurrence is not required to be biopsy
 proven)
- *ACTIVE TREATMENT includes traditional chemotherapy, immunotherapy, radiation, as well as patients on "maintenance therapy" who have known, or existing, metastatic disease being held in check by this treatment. Allogenic bone marrow transplant and CART T_-cell therapy should be considered 'active' treatment for at least 6 months after infusion/transplant and as such can be approved at 30 days, 100 days, and 6 months after the most recent infusion.

**SUBSEQUENT TREATMENT STRATEGY

- For restaging or monitoring response during active treatment (including immunotherapy), and/or a single evaluation after completion/cessation of therapy. The interval should ideally[‡] be 6-12 weeks after surgery, and 12 weeks after radiation (to avoid false positive findings that can be caused by treatment changes or healing).
- PET/CT can be performed 1 3 weeks after neoadjuvant chemotherapy or neoadjuvant chemoradiation if done for presurgical planning to evaluate for distant metastatic disease or to evaluate known metastatic disease located in areas separate from the site(s) being radiated.
 - [‡]NOTE: a valid clinical reason explaining why the interval needs to be shorter than ideal must be present
- INCONCLUSIVE IMAGING see Background section at end of guidelines
- **SURVEILLANCE PET** is generally **not approvable**. Surveillance means no active treatment, no current suspicion of recurrence and occurs 6 months or more after completion of treatment. **Possible exceptions† where PET "may be considered" for surveillance:**

- o Ewing's
- o Osteosarcoma
- Breast (Stage 4)
- Cervical (stage 2-4)
- Diffuse Large B Cell Lymphoma when disease was only seen previously on PET
- Histiocytic neoplasms every 3-6 months for the first 2 years post completion of treatment
- Melanoma (stage 2b-4)
- Myeloma/plasmacytoma (ideally use same type imaging as was used in initial dx, up to 5 yrs after the diagnosis of plasmacytoma)

Seminoma (Stage 2b, 2c and 3)

†NOTE: These cases would need to include a clinical reason why PET is needed (i.e., being considered), rather than conventional imaging (CT, MRI, bone scan). Generally, this would be accepted only when ordered by the treating oncologist or clearly at their recommendation (not as routine follow-up ordered by PCP).

FDG PET

ONCOLOGICAL INDICATIONS FOR FDG PET (SEE SPECIAL TRACERS SECTIONS FOR INDICATIONS OTHER TRACERS)

CANCER TYPE	INITIAL STAGING	RESTAGING
ADRENAL (other than pheochromocytoma/ paraganglioma)	Not Indicated	Not Indicated
AIDS-related KAPOSI SARCOMA	with prior inconclusive imaging	Not Indicated
ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)	lymphomatous extramedullary disease	lymphomatous extramedullary disease
ACUTE MYELOGENOUS LEUKEMIA (AML)	If suspected extramedullary involvement	If suspected/known extramedullary involvement
ANAL (Note that normal size pelvic adenopathy can be considered as inconclusive)	with prior inconclusive imaging (can be done with PET (PET/CT or PET/MR ^{‡‡} if available)).	with prior inconclusive imaging
BASAL CELL (BCC of the skin)	Not Indicated	Not Indicated
BLADDER	Muscle invasive only, with prior inconclusive imaging	With inconclusive imaging and suspected metastatic disease or recurrence outside of the urinary tract
BREAST	Indicated for stage IIb and above (if only T and N are provided, this equates to T3 (tumor > 50mm); or T4 (tumor of any size with direct extension	with prior inconclusive imaging, OR if initial staggingstaging was done-performed with PET OR if recurs with IIb or higher disease (based on

	to chest wall and/or skin); or N2 (>3 axillary LN, ipsilateral internal mammary node); or the combination of T2 (tumor >20mm but <50mm) plus N1 (any positive lymph node involvement)	no previous initial staging would have typically been doneperformed for lower grade breast cancer
CERVICAL	Indicated (can consider PET/MR ^{‡‡} if available)	Indicated
CHORDOMA	with prior inconclusive imaging	Not Indicated with prior inconclusive imaging
CHOLANGIOCARCINOMA	with prior inconclusive imaging	with prior inconclusive imaging
CHONDROSARCOMA (bone)	Not Indicated	Not Indicated
COLORECTAL	with prior inconclusive imaging OROF (PET/CT indicated if potentially surgically curable M1 disease, OROF when considered for imageguided liver_directed therapies)	with prior inconclusive imaging
ENDOMETRIAL	with prior inconclusive imaging	with prior inconclusive imaging
ESOPHOGEAL and EGJ (esophagogastric junction epicenter < 2cm into stomach)	Indicated	Indicated
EWING SARCOMA- Osseous	Indicated (all ages)	Patients <30 yrs old: Indicated Patients >30 yrs old: Indicated for known or suspected

metastatic disease -(based on PE/imaging)-indicated

FALLOPIAN TUBE CANCER

with prior inconclusive imaging

with prior inconclusive imaging

GALLBLADDER

with prior inconclusive imaging

with prior inconclusive imaging

GASTRIC

(include EGJ tumors with epicenter >2cm into stomach)

with prior inconclusive imaging or if radiation is being considered (Not indicated for T1N0M0 or M1) with prior inconclusive imaging PET/CT is indicated or for post radiation imaging

GESTATIONAL TROPHOBLASTIC CANCER

with prior inconclusive imaging

with prior inconclusive imaging

HEAD and NECK (including mucosal melanoma of the head and neck)

Indicated

 May be done in conjunction with a dedicated face/neck MRI_(or CT)_when surgery or radiation is planned

Indicated

- Can concurrently approve a Neck MRI and PET 3-4 months after definitive treatment in patients with locoregionally advanced disease or with altered anatomy.
- PET should not be done earlier than 12 weeks after definitive treatment unless signs or symptoms of recurrence
- If final PET/CT is equivocal or borderline for residual disease, a repeat PET/CT at <u>></u> 6 weeks may help identify those that can be safely observed without additional surgery

HEPATOCELLULAR

with prior inconclusive imaging

with prior inconclusive imaging

LEUKEMIA (refer to specific types listed in table when possible)

If there is lymph node involvement (lymphomatous features), soft tissue and/or extramedullary involvement (myeloid sarcoma) and/or if forms "chloromas" (leukemia tumor balls)

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LUNG

Non-Small Cell

 Limited stage small cell Stage I-III

> And T3/T4 if disease is encompassed in tolerable radiation plan (potentially curable)

Indicated

Indicated

Indicated

Indicated

• Extensive small cell

Stage IV and T3 or T4
 disease not able to be
 treated with curative
 intent

Not indicated

Not indicated

LYMPHOCYTIC LEUKEMIA

Chronic (CLL) and Small (SLL)

For suspected high-grade transformation or to guide biopsy with prior inconclusive imaging

with accelerated CLL or to guide biopsy with prior inconclusive imaging (includes negative CT with rising tumor markers or if conventional imaging documents mets, IF clearly considering resection)

LYMPHOMA (Non-Hodgkins and Hodgkins)

Indicated (can consider PET/MR^{‡‡})

Indicated (can consider PET/MR^{‡‡})

MELANOMA

(See Uveal melanoma below for indications)

only stage III, IV indiceiated

only stage III, IV indicated

MERKEL CELL	Indicated	Indicated
MESOTHELIOMA (malignant) • -PpleuralPleural	Indicated only prior to surgery for stage I-IIIA	Indicated only prior to surgery for stage I-IIIA
 Peritoneal 	Indicated	Indicated
 MULTIPLE MYELOMA Smoldering myeloma (asymptomatic) Active myeloma Plasmacytoma 	Indicated Indicated Indicated	Not indicated (unless labs suggest progression to active myeloma)Indicated annually or possibly ,-more frequently -or as clinically indicated (labs and/or symptoms to suggest progression) Indicated Indicated
NEUROBLASTOMA	Indicated when MIBG is negative, inconclusive, or there are discordant findings between MIBG and pathology	Indicated when the FDG PET was used for initial staging or if MIBG has become inconclusive or discordant
NEUROENDOCRINE TUMORS_(-NET)_WHEN_UNDIFFERENTIATED/DE-DIFFERENTIATED (including pheochromocytoma, paraganglioma, extrapulmonary large/small cell)	Indicated if used after prior negative or inconclusive Ga68 Dotatate scan	Indicated when FDG was used for initial staging, or when used after prior negative/inconclusive Ga68 Dotatate scan (or MIBG scan) OR after inconclusive conventional imaging
OVARIAN	with prior inconclusive imaging	with prior inconclusive imaging
OCCULT PRIMARY	with prior inconclusive imaging (can consider	with prior inconclusive imaging

PET/MR⁺⁺)appropriate to pathology of the biopsy that identified the occult malignancy

OSTEOSARCOMA

Osseous

For patients >30 years old: Indicated when the prior bone scan is inconclusive or negative (i.e., the primary bone tumor is not seen on bone scan). PET can be approved in conjunction with MR of primary site For patients >30 yrs old: Indicated when disease is positive on prior FDG-PET or when there is inconclusive conventional imaging. PET can be approved in conjunction with MR of primary site

For patients <30 years old: Indicated

PET can be approved in conjunction with MR of primary site

For patients <30 years old: Indicated

PET can be approved in conjunction with MR of primary site

PANCREATIC

With prior inconclusive imaging OR with any of the following high-risk features:

- borderline resectable disease
- markedly elevated CA19-9 >180 U/ml
- large primary tumor/lymph nodes
- very symptomatic (jaundice, symptomatic gastric outlet obstruction, venous thromboembolism, extreme pain and excessive weight loss

Not Indicated When PET was used for initial staging and need to assess response to treatment in order to determine if now a surgical candidiate

PENILE

with prior inconclusive imaging

with prior inconclusive imaging

PERITONEAL CANCER (PRIMARY)

with prior inconclusive imaging

with prior inconclusive imaging

POST TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)

Indicated when the diagnosis is made OR if suspected based on abnormal PE, abnormal imaging or abnormal labs (i.e., significantly elevated or rising viral titers)

Indicated

PROSTATE (FDG PET only)

See other PET tracer section below for prostate cancer

Not Indicated

Not Indicated

RENAL

ONLY when conventional imaging is equivocal for metastatic disease and if present would alter initial treatment plan Not Indicated

ONLY when conventional imaging is clearly insufficient in these circumstances:

 For suspected recurrence/metastatic disease outside of the urinary tract

--To determine bland vs tumor thrombosis/emboli

 -To monitor treatment with a Tyrosine Kinase Inhibitor (such as sunitinib, sorafenib) for advanced RCC when disease was only seen previously on PET

SKIN SQUAMOUS CELL

with prior inconclusive imaging

Not Indicated

SMALL BOWEL CARCINOMA

Not indicated

with prior inconclusive imaging

SOFT TISSUE SARCOMA (including soft tissue/extraosseous Ewing sarcoma and soft tissue/extraosseous osteosarcoma)/ GIST/ Rhabdomyosarcoma

For patients >30 years old: with prior inconclusive imaging

For patients <30 years old: Indicated (does not require inconclusive conventional imaging) For patients >30yrs old with prior inconclusive imaging

For patients <30 yrs old: Indicated (does not require inconclusive conventional imaging)

TESTICULAR

Seminoma

Not Indicated

with prior inconclusive imaging or-OR residual mass >3cm with normal AFP and beta-hcG and or 6 weeks post chemotherapy (If this final PET/CT is equivocal or borderline for residual disease PET/CT, a repeatan additional repeat PET/CT a 6 weeks later may help identify those that can be safely observed without additional surgery)

• Non-Seminoma

Not Indicated

Not Indicated

THYMOMA/THYMIC CANCER

Indicated

Indicated

THYROID

• Papillary, Follicular, Hurthle Not I

Not Indicated

Indicated with the following 3 criteria:

- A thyroidectomy and radioiodine ablation were done initially; AND
- Serum thyroglobulin (Tg) is >2 ng/ml (unstimulated or stimulated) OR there is a high anti- thyroglobulin antibody (anti-Tg Ab) >1 year after treatment AND
- A Negative current I-131/I123 scan OR a Negative
 prior stimulated whole body
 I-131/ I-123 scan done at
 Tg← level similar to the

current TgG level (a current scan is needed if on radioiodine sensitizing medications)

Hurthle
 If Tg is high and/or pathology

is high-risk IF Tg

IF Tg is high and/or pathology is

high-risk Anaplastic

With prior inconclusive imaging With prior inconclusive imaging

Not Indicated (see

Medullary

NET/Dotatate indications

below)

<u>W</u>with prior inconclusive imaging when calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery with prior insufficient Dotatate scan

UTERINE with prior inconclusive imaging with prior inconclusive imaging

UVEAL MELANOMA Not Indicated with prior inconclusive imaging

VAGINAL Indicated Indicated

VULVAR ≥T2 or after prior inconclusive Indicated

imaging

MISCELLANEOUS (NON-ONCOLOGIC) INDICATIONS FOR FDG PET

(excluding brain and cardiac PET which have separate Guidelines)

TYPE INITIAL STAGING RESTAGING

CASTLEMAN'S DISEASE Indicated Indicated

MISCELLANEOUS (NON-ONCOLOGIC) INDICATIONS FOR FDG PET

(excluding brain and cardiac PET which have separate Guidelines)

TYPE	INITIAL STAGING	RESTAGING
HISTIOCYTIC NEOPLASMS:		
•Langerhan's	Indicated	Indicated if on active treatment for multiple bone disease, high risk bone disease or multisystem involvement
Erdheim ChesterRosai-Dorfman	Indicated Indicated	Indicated if on active treatment Indicated if on active treatment
-Erdheim Chester -Rosai-Dorfman		ndicated if on active treatment ndicated if on active treatment

*SARCOIDOSIS

ONLY if conventional testing (CXR, CT and inflammatory serology) –remain inconclusive
 to determine: for known sarcoid to determine:

•

	———— if treatment might be helpful
<u>O</u>	
	extent of disease, if it will potentially change management
<u>O</u>	
0	-most suitable site to biopsy
	response to treatment
0	

• ____OR if <u>s-Strongly supected sarcdoid to determine</u> <u>-most suitable site to biopsy</u>

*VASCULITIS:

In limited circumstances, with known vasculitis, AFTER conventional imaging (MRA/CTA/MR/CT) hasve clearly been shown to be insufficient to determine treatment

^{*}Adjudications should occur on a case-by-case basis by a PET PCR.

NON FDG PET TRACERS

OTHER (NON-FDG) PET TRACERS covered

GA68-DOTATATE, GA68-DOTATOC and CU64-DOTATATE

FOR NET (Neuroendocrine Tumors)

CANCER TYPE	INITIAL STAGING	RESTAGING
CARCINOID EXTRAPULMONARY LARGE AND SMALL CELL MEN-1/MEN-2 SYNDOMES NEUROENDOCRINE TUMORS (NET) PHEOCHROMOCYTOMA PARAGANGLIOMA	• Indicated • (can consider PET/MR ^{‡‡}) ^{‡‡} can be considered	 Indicated PET/MR^{‡‡} can be considered
MEDULLARY THYROID	 Prior CT/ MRI insufficient to Determine extent of treatment plan Determine if candidate for invasive diagnostic/ therapeutic procedure Determine optimal anatomic location for invasive procedure 	When calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery

YTTRIUM-90 (Y90)

Y90 PET SCAN: Indicated when doneperformed immediately after treatment of liver malignancy (primary or metastatic) with Y90 (usually within 24 hours while the Y90 is still detectible). The Y90 treatment is the tracer for this PET (see Y90 background section).

PSMA TRACERS (such as F18 piflufolastat (Pylarify®), GA 68 PSMA-11, and GA 68 gozetotide (Locametz®), and GA 68 gozetotide (Illuccix®)); F18 FLUCICLOVINE (AXUMIN®) and C11 CHOLINE

For PROSTATE CANCER

CANCER	INITIAL STAGING	RESTAGING
PROSTATE (PET/CT or PET/MRI**) After a negative Axumin® PET, a subsequent PSMA PET is not covered until a repeat PSA (done at least 3 months later) shows a progressive rise 11-Choline should be approved only if PSMA and/or Axumin® are not available. Order of preference typically would be PSMA, then Axumin®, then 11-Choline	Only PSMA (not Axumin® or Choline) is indicated in initial staging for high risk; defined as 1 or more of the following: • Gleason 8, 9 or 10 (specimen contains pattern 4 or 5) • Gleason 7 IF primary pattern** is 4 (4+3=7) • Gleason 7 primary pattern 3 (3+4=7) must ALSO have a PSA >10 and/or cT2b-cT3c disease • Gleason 6 disease (3+3=6) must ALSO have a PSA > 20 and/or cT3a-cT4 disease • >50% cores positive for cancer in random biopsy **The Primary Pattern refers to the 1st number in the Gleason Pattern	For post-surgery/radiation in suspected recurrence with- at least two separate detectable PSA levels above the nadir for that patient withfor:
	Pelvic MRI can be approved concurrently if needed for surgical planning	For post surgery/radiation in known recurrence, PSMA is approvable if:
		Patient is a candidate for Lu- PSMA treatment (Pluvicto)
		(must be clearly documented in
		note) typically metastatic
		castrate resistant disease

Restaging on Lu PSMA treatment (Pluvicto)

 Disease was previously seen only on PSMA PET

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For metastatic castrate
resistant disease that have
failed both taxanes and ARDI,
PSMA is approvable if:

- Individual is a
 candidate for Lu-PSMA
 treatment (Pluvicto®)
 (must be clearly
 documented in note)
- Restaging on Lu-PSMA treatment (Pluvicto®)

BACKGROUND

Inconclusive Imaging includes the following:

- Equivocal or ambiguous other prior standard imaging if results will change management
- Biopsy guidance (e.g., tumors with necrosis)
- High suspicion of metastases due to clinical or histopathological or laboratory considerations but with no evidence of metastases on standard initial staging
- Clinical or laboratory disease progression with negative standard imaging
- Contraindications to IV contrast, including allergy and chronic renal failure precluding MRI in a patient with a known or highly suspected malignancy
 - PET/CT may be indicated if CT cannot be performed due to significant iodinated contrast allergy or chronic renal failure AND MRI cannot be performed due to significant gadolinium contrast allergy or if renal failure with GFR < 30.²
- Evaluation for other distant metastases prior to surgical resection of limited metastases/local disease and otherwise negative prior standard imaging
- Response to neoadjuvant therapy when CT/MR insufficient
- Residual masses after completion of therapy
- Target definition for radiation planning
- If previous conventional imaging has been inconclusive, and it seems reasonable to expect that to still be the case, new conventional imaging is NOT required

In situations where there is questionable disease in an area that requires significantly invasive procedures to obtain tissue (such as open surgical procedures), and malignancy is high on the radiographic differential diagnosis, it is reasonable and medically appropriate to attempt to gain

as much information about diagnosis from imaging prior to subjecting the patient to tissue diagnosis that has real risk of morbidity/mortality.

Definition of Disease Progression:

For any signs of progression, as noted below, that could not be confirmed by other imaging, PET/CT is needed. Findings concerning for progression of disease include:

- Worsening of symptoms such as pain or dyspnea
- Evidence of worsening or new disease on physical examination
- Declining performance status
- Unexplained weight loss
- Increasing alkaline phosphatase, alanine aminotransferase (ALT), aspartate transaminase (AST), or bilirubin
- Hypercalcemia
- New radiographic abnormality or increase in the size of pre-existing radiographic abnormality
- New areas of abnormality on functional imaging (e.g., bone scan, PET/CT)
- Increasing tumor markers (e.g., carcinoembryonic antigen [CEA], CA 15-3, CA27.29)
- To help differentiate possible recurrent/active tumor from necrotic or inactive scartissue, malignant from benign tissue, and nondescript-benign changes.

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• PET/CT also helps to differentiate active tumor from necrotic or inactive scar tissue, malignant from benign tissue, and recurrent tumor from nondescript benign changes.

PET and separate CT/MR: PositronPositron emission tomography-Computed Tomography (PET/CT) is a rapidly developing and changing technology that is able to detect biochemical reactions, e.g., metabolism, or abnormal distribution of cell receptors within body tissues. A radioactive tracer is used during the procedure. Unlike other nuclear medicine examinations, PET/CT can measure metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET/CT may also detect biochemical changes that help to evaluate malignant tumors and other lesions.

TYPICALLY, separate CT/MR scans being requested concurrently with a PET are not needed. There should be very few instances where separate studies are needed, and when this does happen, it is usually SITE-SPECIFIC. Most PET scanners now in use can "simultaneously" perform PET and CT (whether <u>for</u> CT Attenuation or a Diagnostic CT). Contrast can be given for the CT portion of the PET/CT. A separate request for diagnostic CTs in addition to PET is, therefore, not needed. The ordering MDO can specify to the imaging provider details about what type of CT scan is desired to be done with the PET portion. "Exceptions" generally occur when CT is needed in a plane other than standard axial imaging (for example: coronal CT for facial bone imaging that might be needed for surgical reconstruction). Separate MRIs are likewise rarely needed, but are perhaps somewhat more frequently needed than additional, separate CTs, since MRI does allow multiple imaging planes and may provide additional information. When

evaluating for these "exceptions", the reason additional separate imaging is needed should be clearly delineated before approval.

The degree of radioactive tracer uptake may indicate increased metabolism in the cells of body tissues or an abnormal distribution of cell receptors. Cancer cells may show increased radioactive tracer relative to tissue not involved with tumor. Radioactive tracer uptake is often higher in fast growing tumors; PET/CT is often not as beneficial for slow growing tumors. Radioactive tracer uptake may occur in various types of active inflammation and is not specific for cancer. FDG is the most widely known and frequently requested radiotracer; however, the use of "special tracers" is a rapidly progressing field. These "special tracers" are typically somewhat specific to a certain cancer type due to their physiological properties. As such, a particularly careful review should be made when there is concern that a "special tracer" is needed or requested, regardless of whether the ST icon is present... If the notes clearly indicate the desired tracer (and guidelines are met for the tracer and cancer type), the case should be adjudicated according to the notes rather than the presence or absence of the ST icon. However, if the notes do not clearly indicate what tracer is requested, this needs to be clarified when there is discrepancy between notes and the ST icon (or lack thereof). the tumor type may require a tracer other than FDG.

Patients with certain malignancies may benefit more from PET/MRI since it detects brain and liver metastases better when compared with PET/CT. NCCN does suggest consideration of PET/MR in some malignancies (see table for specific cancers), but not specifically for replacing PET/CT. PET/MRI should only be considered for certain malignancies and in specific situations (such as when extensive travel would be needed, for pediatric cases, particularly those requiring sedation or when reasonably expect a need for multiple PET scans where radiation exposure from CT would be a significant factor). Typically, PET/CT should suffice; however, under some circumstances, with clear explanation of why PET/MR is preferred rather than PET/CT, PET/MR may be an appropriate study**.

##++ PET/MR: Patients with certain malignancies may benefit from PET/MRI since it detects brain and liver metastases better when compared with PET/CT. NCCN does suggest consideration of PET/MR in some malignancies, but not specifically for replacing PET/CT. PET/MRI should only be considered for those specific malignancies (see table for specific cancers) and in certain situations. Typically, PET/CT should suffice; however, under some circumstances, with clear explanation of why PET/MR is preferred rather than PET/CT, PET/MR may be an appropriate study. We are not currently able to approve PET/MRI's and must refer the MDO to HP. Currently, there is no CPT code for PET/MR. As noted in our GLs, PET/MR may be considered only for a few specific certain cancers, and it typically would only be those that would need to be referred to the HP directly.

<u>Langerhans Cell Histiocytosis is the most common type of histiocytosis, with variable</u>
<u>presentations and sites involvement.</u> <u>Some studies suggest PET/CT may be more effective in detecting bone lesions compared with MRI and bone scans in assessing disease response as</u>

<u>healing/treatment changes of bone lesions on conventional imaging may be delayed. However, PET/CT is not the modality of choice in assessing disease response of lung or brain lesions.</u>

Y90 PET Scans:

Hepatic radioembolization, involving Radioembolization with Y90 intraarterial injection of yttrium-90 (Y90)-labeled glass or resin microspheres, is used for liver_-dominant malignancy or metastases that are unresectable. (such as hepatocellular carcinoma or metastatic colon cancer among others). It involves intraarterial injection of yttrium 90(Y90) labeled glass or resin microspheres. A Tc99m MAA nuclear scan (typically requiring SPECTsimilar in size to the Y90 microspheres) is done-performed before the actual treatment with Y90. MAA, which is similar in size to the Y90 microspheres, MAA mimics the distribution of the Y90 particles and selective arterial injections should embolize within the tumor's hepatic arterioles, thus outlining the expected localization of the radiation. The scan is compared to a CTA/MRA to evaluate for any possible shunting of the treatment agent to the lungs or the GI tract. Coils can be placed as needed to minimize any shunting of Y90 to areas other than the desired target.

Post-procedure imaging (within 24 hours) with either SPECT or PET (at the discretion of the treating physicians) is then done-performed to confirm the final distribution of the Y90 and to calculate the actual radiation dose delivered to the tumor. Utilizing the Bremsstrahlung radiation of the Y90 embolization agent, SPECT, (or SPECT/CT) can be done-completed with routine nuclear medicine collimators. However, due to it-their higher energy level (as compared to routine nuclear medicine agents)—, the Y90 photons scatter and/or pass through the collimator septa and degrade the image quality. Alternatively, PET scanning can be done, again using the Y90 treatment agent itself, but for PET via a minor decay pattern that emits a positron (32 in every one million decays) that is detectable with PET scanners.

FDG PET may be needed later (ideally performed >12 weeks after treatment) to access tumor response to this radiation, in accordance with the tumor_-specific gudielines for FDG PET restaging (in the table above) so-and may still require inconclusive conventional imaging, if necessary for the type of cancer being treated.

POLICY HISTORY

POLICY HISTORY	1.	
Date	Summary	
June-May 2022	 Updated changes for based on NCCN including updates most notabelly for prostate cancer, Hurthle, NETs Clarified when PET may be approved prior to biopsy for lung nodules and when PET is unnecessary (e.g., disease clearly present in both sides of chest and/or outside the chest) Added some indications for rare specific histiocytic syndromes, and for sarcoid and vasculitis for non-oncological indications Added restaging for RCC and pancreatic cancer in specific situations Added information about indications for Y90 PET scan (liver malignancy) Updated definitions of clinical guidelines (PET, PET/CT, and PET with CT Attenuation) Minor wording clairifcationsclarifications, table adjustments 	
June 2021	 Added: Definitions CART T info PTLD information added PET/MRI information Updated/added details for Prostate cancer and PSMA, Axumin and Choline Minor adjustments to the PET FDG table, such as added details from NCCN, clarifications, separation of non-malignant uses 	
May 2020	 Modified to table format Added section of follow up of a new or interval growth of a mixed pulmonary lung nodule on subsequent LDCT (NCCN 2020) Initial staging indicated Changed AML to extramedullary disease (previously lymphomatous involvement) Changed Breast cancer stage IIb and above (previously III and IV) Added Castleman's disease Added for Chronic Lymphocytic Leukemia to guide biopsy Changed Mesothelioma to only prior to surgery for stage I-IIIA Added "soft tissue" sarcoma in pediatric patient 	

- Added Thymoma and thymic cancer
- Added Langerhans Cell Histiocytosis-predominantly osseous disease (previously not included)
- Initial staging which is only indicated after prior inconclusive imaging (NCCN 2019/2020)
 - Added AIDS related Kaposi sarcoma
 - Changed Anal carcinoma (previously indicated)
 - Added Ewing sarcoma-osseous
 - Added Gestastional trophoblastic disease
 - Added Hepatocellular/Intrahepatic Cholangiocarcinoma (previously not included)
 - Added Fallopian tube and primary peritoneal cancer
 - Added Osteosarcoma-osseous
 - Changed Penile cancer (previously indicated with palpable nodes)
- Initial staging NOT indicated (NCCN 2019/2020)
 - Changed testicular (previously indicated)
 - Added Uveal Melanoma
 - Added Langerhans Cell Histiocytosis-predominantly nonosseous disease (previously not included)
- Restaging indicated (NCCN 2019/2020)
 - Added Castleman's disease
 - Added for accelerated Chronic Lymphocytic Leukemia and to guide biopsy
 - Added Gastric Cancer post radiation treatment
 - Changed Mesothelioma to only prior to surgery for stage I-IIIA
 - o Added "soft tissue" to sarcoma in pediatric patient
 - Added Thymoma and thymic cancer
 - Added Langerhans Cell Histiocytosis-predominantly osseous disease (previously not included)
- Restaging which are only indicated after prior inconclusive imaging (NCCN 2019/2020)
 - o Removed for resectable disease in Colorectal cancer
 - Removed for if candidate for surgery/locoregional therapy for endometrial cancer
 - Specified Ewings sarcoma-osseous
 - Added Extrahepatic Cholangiocarcinoma (previously not indicated)
 - Added Gallbladder carcinoma (previously not indicated)
 - Changed Gastric Cancer to prior inconclusive imaging or if radiation planning considered (previously indicated if no metastasis or early disease)

- Added Gestastional trophoblastic disease
- Added Hepatocellular/Intrahepatic Cholangiocarcinoma (previously not included)
- Changed Ovarian cancer (previously indicated for greater than Stage I)
- Added Fallopian tube and all stages of primary peritoneal cancer
- Added Osteosarcoma- osseous
- Added that for pheochromocytoma/ paraganglioma, extrapulmonary large/small cell, restaging FDG PET/CT can be done after inconclusive CT
- Modified Seminoma with residual mass >3cm or 6 weeks post chemotherapy (previously indicated)
- Added Uveal melanoma
- Restaging NOT indicated (NCCN 2019/2020)
 - o Added AIDS related Kaposi sarcoma
 - Changed Testicular non seminoma (previously indicated)
 - Added Langerhans Cell Histiocytosis-predominantly nonosseous disease (previously not included)
- Added CT face/neck may be done in conjunction with PET when surgery or radiation is planned
- Added to head and neck cancer that if a final PET is equivocal or borderline for residual disease PET, a repeat PET/CT a > 6 weeks may help identify those that can be safely observed without additional surgery
- Medullary thyroid: added FDG restaging indicated when CEA
 >5ng/ml post-surgery and after prior insufficient Dotatate scan
- Modified pancreatic cancer symptoms to excessive weight loss
- Added to Seminoma: if final PET is equivocal or borderline for residual disease PET, a repeat PET/CT a

 6 weeks may help identify those that can be safely observed without additional surgery)
- Thyroid FDG- changed serum thyroglobulin level to >2ng/ml (previously >5ng/ml) and added 'current OR two prior stimulated whole body I-131/ I-123 scans are negative (a current scan is needed if on radioiodine sensitizing medications)'
- GA⁶⁸ Dotatate- added restaging calcitonin levels ≥ 150 pg/ml or CEA levels >5 ng/ml post-surgery
- F18 Fluciclovine (Axumin)
 - Initial staging changed to: With prior inconclusive bone scan with no CT/MRI correlate; or inconclusive bone SPECT/CT

 Restaging changed to with rising/persistent PSA and after CT/MRI has been performed and is insufficient for detection of metastases Added Inconclusive imaging features to background as noted in **NCCN 2020** Added Disease progression to Background as noted in NCCN Added Section of Langerhans Cell Histiocytosis to background section September 2019 Removed Introduction section Removed "Important Note" Changed title "The following are noncovered for all other indications including (but not limited to):" to "The following are noncovered for F18 FDG, Ga68 Dotatate, F18 Fluciclovine_(NCCN 2019):" • Under noncovered for F¹⁸ FDG, Ga⁶⁸ Dotatate, F¹⁸ Fluciclovine section, added the following: o Breast cancer - Initial Staging for Stage I and II Breast Cancer Melanoma - Initial and Restaging for Stage I and II Melanoma (NCCN 2016) o Bladder Cancer - non muscle invasive (by imaging or tissue sample) • Vulvar Cancer < T2 or no suspicion of metastatic disease Prostate Cancer - Initial or Restaging o Small cell lung cancer - Staging (Initial or Restaging) for extensive disease Ovarian Cancer - Restaging if stage I Pancreatic Cancer - Restaging Renal Cancer - Initial and Restaging Skin Squamous Cell Carcinoma - Restaging o Gastric Cancer - Initial staging if there is evidence of metastases (M1), or very early disease (T1) o Malignant Pleural Mesothelioma - Initial staging except if stage I-IIIA and pre-surgical Hepatocellular / Intrahepatic Cholangiocarcinoma -**Initial and Restaging** Gallbladder/ Extrahepatic Cholangiocarcinoma -Restaging o Small bowel adenocarcinoma - Initial Staging Chordoma – Restaging

- Adrenal (except pheochromocytoma/ paraganglioma) -Initial or Restaging
- Smoldering Myeloma except to discern smoldering from active myeloma with negative skeletal survey
- ALL (Acute Lymphoblastic Leukemia) / AML (Acute Myelogenous Leukemia) - Unless prior imaging suggests lymphomatous involvement
- o BCC (Basal Cell Carcinoma (of the skin))
- Infection and/or Inflammation: removed "- PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin."
- Under indications for oncological PET heading, added: "Note: for radiation treatment planning, contact health plan directly"
- Under Initial Treatment Strategy, the first sentence now specifies "active myeloma" instead of "myeloma" previously
- Under Initial Treatment Strategy, the last sentence now replaces "after a" with "AND": "To determine the optimal anatomic location for an invasive procedure AND prior imaging insufficient"
- "CLL chronic lymphocytic leukemia (PET/CT is generally not useful in CLL/SLL but may be necessary to direct nodal tissue sampling when high-grade histologic transformation is suspected) (NCCN, 2018)." has been changed to "CLL (Chronic Lymphocytic Leukemia): only when high-grade histologic transformation is suspected (NCCN, 2018)"
- Changed references for SPN to "(Bueno, 2018; MacMahon, 2017)" from previous "(Vansteenkiste, 2006)"
- Removed the section:
 - " Excluding
 - ALL- acute lymphoblastic leukemia
 o Unless prior CT imaging suggest lymphomatous
 involvement
 - AML acute myelogenous leukemia
 O Unless clinical suspicion for extramedullary disease
 - BCC basal cell carcinoma (of the skin)
 - Prostate cancer (NCCN, 2018)"
- Added "EXCEPT for the following, which are only indicated after prior inconclusive imaging (NCCN 2019):
 - Colorectal
 - Ovarian/ fallopian
 - Sarcoma/ GIST/ Uterine/Rhabdomyosarcoma
 - o Chordoma
 - Muscle invasive bladder cancer

- o Endometrial Cancer
- Penile (for palpable nodes only)
- Occult Primary
- Pancreatic Cancer (unless high risk features: borderline resectable, markedly elevated CA19-9 > 180 U/ml, large primary tumor/ lymph nodes)
- Skin squamous Cell Carcinoma
- Gallbladder/ Extrahepatic Cholangiocarcinoma
- Poorly differentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan (includes Pheochromocytoma/ paraganglioma, extrapulmonary large/small cell)"
- Under subsequent Treatment Strategy, first line has been modified by adding parenthesis as follows: Restaging or monitoring response to active treatment (including immunotherapy)"
- Under subsequent Treatment Strategy, changed "not to be performed within 4 weeks of completion of therapy (ideally F¹⁸ FDG, Ga⁶⁸ Dotatate, F¹⁸ Fluciclovine PET is delayed 2 3months after surgical therapy, 2 3 months after radiation therapy if locoregional assessment is the imaging goal), and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms. (Asymptomatic surveillance is not approvable) (NCCN, 2018)." to "The interval should ideally be 6 12 weeks after surgery, and 12 weeks after radiation. PET can be performed 1-3 weeks after neoadjuvant chemotherapy or neoadjuvant chemoradiation to assess stage for surgery. PET evaluation can also be done for suspicion of recurrence due to new or changing signs/symptoms or rising tumor markers, or inconclusive findings on CT. Asymptomatic surveillance is not approvable. (NCCN 2018, 2019)"
- List of cancers under subsequent imaging (without needing prior inconclusive imaging) has been changed. The following were removed: Breast cancer (female and males), colorectal cancer (including colon, rectal, appendiceal or anal cancer), ovarian cancer. The following were changed as follows:
- "Lung cancer Non-small cell" to "Lung cancer Non-small cell and limited stage small cell cancer"
- "Esophageal cancer" to "Esophageal and esophagogastric cancer"
- "Melanoma" to Melanoma- only stage III, IV (excludes uveal melanoma)
- "Myeloma to "Active Myeloma/plasmacytoma"

- Added for Soft tissue sarcoma: "only stage II/III for response to neoadjuvant Rx"
- Added Merkel cell carcinoma
- Added "Mesothelioma, if also presurgical"
- Individual References were removed for soft tissue sarcoma and vulvar/ vaginal cancer.
- Statement regarding subsequent PET scans needing prior inconclusive imaging has been modified from "only" if other imaging (ie. US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed "to "only if other imaging (ie. US, CT, MRI, NM) is inconclusive/ insufficient in determining a treatment plan or unable to be performed or with rising tumor markers and negative/ insufficient other imaging. PETCT is to be used only if the cancer is known to be generally F¹⁸ FDG, Ga⁶⁸ Dotatate, F¹⁸ Fluciclovine avid. It may be indicated if iodinated and gadolinium contrast are both contraindicated due to significant allergy or chronic renal failure without dialysis (NCCN 2019). "
- Under subsequent PET scans needing prior inconclusive imaging, the following were changed:
 - Added: Breast cancer (female and males), Bladder cancer, only if metastatic, Colorectal Cancer resectable metastatic disease only, Anal/ Vulvar/ Penile Carcinoma, Bone Sarcoma, Sarcoma/ GIST/
 Uterine/Rhabdomyosarcoma, Ovarian/ malignant germ cell tumors/primary peritoneal cancer Stage II-IV, Endometrial cancer if candidate for surgery/locoregional therapy; Poorly differentiated Cancers, or Dedifferentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan
- Removed: prostate cancer, pancreatic cancer, individual references for cancers
- Changed: "Lung cancer -Small cell" to "Extensive small cell lung cancer"; "Tumor of unknown Origin" to "Occult primary"; "Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc)" to "Poorly differentiated or dedifferentiated neuroendocrine tumors with prior negative Ga68 Dotatate/ MIBG/Octreotide scan (includes Pheochromocytoma/ paraganglioma, extrapulmonary large/small cell)".
- Last sentence has been changed from "Other malignancies where the tumor has been shown to be F¹⁸ FDG, Ga⁶⁸ Dotatate, F¹⁸ Fluciclovineavid on prior PET/CT imaging if done, and other imaging (ie: US, CT, MRI, NM) is inconclusive in determining a

treatment plan or unable to be performed " to "Other malignancies where other imaging (i.e., US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed."

- Under thyroid Cancer,
 - Added references "(NCCN 2019, ATA 2015)" to subsequent treatment strategy for papillary/follicular/ hurthle cancers
 - Changed "Stimulated serum thyroglobulin > 2
 ng/ml" to "Stimulated serum thyroglobulin > 5
 ng/ml or high anti- thyroglobulin antibody (anti-Tg Ab) > 1 year after treatment (Na SJ 2012)"
 - Changed "Current whole body I-131 scan is negative (Kloos, 2005)" to "Current stimulated whole body I-131/ I-123 scan is negative (Alzahranj 2012)"
 - Changed "Medullary thyroid cancer when calcitonin levels > 150 pg/ml post-operatively (Wells, 2015)" to "Medullary thyroid cancer when calcitonin levels ≥ 150 pg/ml post primary treatment (NCCN 2019, Souteiro 2019)"
 - Changed "Anaplastic 3-6 months after initial treatment, 3-6 month interval if persistent structural disease (Smallridge, 2012)" to "Anaplastic: Initial and Restaging after prior inconclusive/ insufficient CT/MRI (NCCN 2019)"
- Added pediatric cancers section as follows: "PEDIATRIC CANCERS (for indications different from adult guidelines):
 - Sarcoma Initial and Restaging (Quartuccio 2015)
 - Neuroblastoma/ other cancers under Ga68 imaging: only with prior negative/ inconclusive MIBG/
 Octreotide/ Ga68 PETCT (Uslu 2015, Alexander 2018, Kong 2016, Li 2018, Elkhatib 2017)
 - Nasopharyngeal Cancer- Initial staging after inconclusive/ insufficient MRI; Restaging. (Cheuk 2012)
- For Gallium 68 Dotatate PET:
 - Added references for initial or subsequent treatment strategy: (NCCN 2019, Deppen, 2016 a, b)
 - Added under neuroendocrine tumors: "Medullary Thyroid Cancer for Initial staging; and Restaging when calcitonin ≥ 150 pg/ml"

- Modified last part of the last sentence as follows: "and rising biomarkers (asymptomatic surveillance is not approvable). "
- Under 18F-Fluciclovine PET/CT SCAN:
 - o Added "(Axumin)" after 18F-Fluciclovine
 - o Removed reference "(Bach-Gansmo, 2017)"
 - Changed "18F-Fluciclovine PET/CT scans should be performed only if other imaging (CT, MRI, US, NM) is inconclusive/insufficient AND the patient has not already been evaluated with an F18 FDG, Ga68 Dotatate, F18 Fluciclovine PET/CT Scan" to "Known prostate cancer for workup of recurrence and response to treatment, only if other imaging (CT, MRI) AND Bone scan is inconclusive/insufficient. (NCCN 2019, Andriole 2019, Bach-Gansmo 2017)"
 - Removed:" Known prostate cancer for workup of recurrence and response to treatment:"
 - "Initial treatment by radical prostatectomy with" was replaced by "Post radical prostatectomy with"
 - "Initial treatment radiation therapy with" was replaced by "Post radiation therapy with"
 - "Post-RT rising PSA or positive digital exam and is candidate for local therapy" was replaced by "rising/persistent PSA (increase should be >2ng/ml unless doubling time ≤ 8 months or pt is a candidate for local salvage therapy)"
- Removed: "NOTE: Not all plans cover 18F-Fluciclovine (A9588), such as Magellan Complete Care of Florida and Magellan Complete Care of Arizona. If you are unsure, you should check with the Health Plan prior to requesting a PET with Fluciclovine from NIA."
- Added Background section as follows:
 "BACKGROUND:

Positron emission tomography (PET) is a rapidly developing and changing technology that is able to detect biochemical reactions, e.g., metabolism, or abnormal distribution of cell receptors within body tissues. A radioactive tracer is used during the procedure. Unlike other nuclear medicine examinations, PET can measure metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET may also detect biochemical changes that help to evaluate malignant tumors and other lesions.

The degree of radioactive tracer uptake may indicate increased metabolism in the cells of body tissues or an abnormal distribution of cell receptors. Cancer cells may show increased radioactive tracer relative to tissue not involved with tumor. Radioactive tracer uptake is often higher in fast-growing tumors; PET is often not as beneficial for slow growing tumors. Radioactive tracer uptake may occur in various types of active inflammation and is not specific for cancer."

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ADDITIONAL RESOURCES

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The value of yttrium-90 PET/CT after hepatic radioembolization: a pictorial essay
Ahmed A. Alsultan, Maarten L. J. Smits, Maarten W. Barentsz, Arthur J. A. T. Braat & Marnix G.
E. H. Lam

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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